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STATE WATER RESOURCES CONTROL BOARD RESOLUTION NO. 2020-

ADOPTING REGULATIONS FOR ACCREDITATION OF ENVIRONMENTAL LABORATORIES IN TITLE 22, CALIFORNIA CODE OF REGULATIONS, SECTIONS 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860

WHEREAS:

1. Effective stewardship of the environment and protection of public health requires quality data to inform state agencies of the effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or the toxicity of sediments in rivers.
2. Field and laboratory methods are often complex and analytical instrumentation evolve as technology improves. Through the use of accreditation to oversee laboratories that provide these analytical services to the State, the State is able to ensure that laboratories generate data of a known minimum quality, that data obtained from different laboratories are comparable, and all laboratories comply with the same set of regulatory standards.
3. The 1994 Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090), and Chapter 19 of Division 4 of Title 22 of the California Code of Regulations (CCR), provides the Environmental Laboratory Accreditation Program (ELAP) authority and structure to accredit laboratories for the analysis of environmental samples for regulatory purposes;
4. The federal Safe Drinking Water Act requires the state provide a program for the certification of laboratories and the authority to carry out such a program. (42 U.S.C. §300g-2 and 40 C.F.R. §142.10 (b)(3)(i).);
5. ELAP's current regulations have not been updated since 1994 and lack the specificity and details necessary for effectively regulating laboratory performance and creating standardized practices in laboratories to ensure data quality. These proposed regulations address those issues and will meet the statutory requirements and intent of the Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090);

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6. In 2015 an Expert Review Panel identified a number of fundamental weaknesses that hinder ELAP's ability to achieve its mission of ensuring the State has access to quality data for use in its environmental decision making and observed that these deficiencies have cost the program credibility among key constituencies – notably, the state agencies that rely on data generated by ELAP-accredited laboratories;
7. "Data quality" is defined by ELAP's regulatory agency partners, who are the primary users of the data created by the laboratories, as accuracy of results, consistency and comparability of results across laboratories, robust quality assurance requirements, and legal defensibility;
8. The adoption of these regulations will help ELAP implement a sustainable accreditation program that ensures laboratories generate environmental and public health data of known, consistent, and documented quality to meet stakeholder needs, and that California uses the highest quality scientific data as a foundation for its environmental and public health programs and decisions.
9. The proposed changes to the regulations will be contained in Title 22, California Code of Regulations, sections 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860.
10. On October 11, 2019, the State Water Board published a notice of proposed rulemaking pursuant to the requirements of the California Administrative Procedures Act (APA), initiating a 70-day comment period, which ran from October 11, 2019 to December 20, 2019;
11. State Water Board staff held a public hearing on December 18, 2019. The purpose and intent of the public comment period and public hearing were to receive written and oral comments from the public on the proposed regulations in accordance with the APA;
12. An additional 15-day public comment period was provided from February 13, 2020 to February 28, 2020 to allow the public to comment on changes made to the proposed text of the regulations in response to comments received during the 70-day public comment period;
13. Prior to the adoption hearing, the State Water Board staff provided to the State Water Board summaries of, and response to, the comments received during the two comment periods, which was also made available to the public;
14. Final responses to all comments that were received during the public comment periods will be prepared and contained in the Final Statement of Reasons and submitted to the Office of Administrative Law (OAL) as part of the regulations package; and

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15. With the exception of the 2016 TNI Standards, which was made available online through TNI, all elements of the regulatory package are posted on the program webpage at:
https://www.waterboards.ca.gov/drinking_water/certlic/labs/elap_regulations.html
16. As allowed per the OAL's regulations, the 2016 TNI Standard is being incorporated by reference into the proposed regulations. (Cal. Code Regs., tit. 1, § 20.) The TNI Standard contains relevant language from the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards, which are copyright protected, and the 2016 TNI Standard is provided through a license agreement. During the development of the regulations, including during the public comment period, the State Water Board made the 2016 TNI Standard publicly available for viewing at the CalEPA Headquarters Office in Sacramento, each of the nine (9) Regional Water Quality Control Board Offices, and twenty-four (24) Division of Drinking Water District Offices. Interested parties were able to contact any of those offices to view the 2016 TNI Standard in the designated public record document review area. Additionally, The NELAC Institute provided access to a read-only, unlicensed version of the 2016 TNI Standard for all interested parties on the [TNI website](#). The 2016 TNI Standard was also available for purchase from TNI at a discounted rate.

THEREFORE BE IT RESOLVED THAT:

The State Water Board

1. Adopts the proposed ELAP Regulations, which will make modifications to Title 22, California Code of Regulations, sections 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860, as appended to this Resolution;
2. Incorporates by reference into the regulations the 2016 TNI Standards – Revision 2.1, Volume 1, “Management and Technical Requirements for Laboratories Performing Environmental Analysis,” with two California-specific exceptions, and directs staff in the final statement of reasons to set out how it would otherwise be impractical to publish the TNI Standards in the California Code of Regulations and how the document was made available to the public during the public comment period. The standard will continue to be reasonably available to the public by purchase from TNI.
3. Water Code section 106.3 established a state policy that every human being has the right to safe, clean, affordable, and accessible water adequate for human consumption, cooking, and sanitary purposes, and requires the State Water Board to consider this policy when revising, adopting, or establishing regulations when those regulations are pertinent to the uses of water

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described in the policy. This policy, which is referred to as the Human Right to Water, was considered by the State Water Board as part of the adoption of these regulations, and it was concluded that the regulations further the policy by setting specific requirements for laboratories that conduct analysis of water for regulatory purposes, helping to ensure that the laboratories are able to run the methods required by the regulations, and creating standardized practices to ensure that results are accurate, consistent and comparable between laboratories, reflect robust quality assurance requirements, and are legally defensible;

4. Adopts a single laboratory accreditation standard that incorporates quality management requirements. All data produced for regulatory environmental purposes and environmental decision-making are produced for the same broad purpose, and therefore will be subject to a single standard that will help provide data of equal quality regardless of a laboratory's size, type, geographic location, or community's economic status.
5. Directs State Water Board staff to:
 - a. Prioritize its resources to assist laboratories with transitioning to these regulations through a variety of tools and trainings throughout a 3-year Transition Period beginning upon the effective date of the regulations.
 - b. After the 3-year Transition period prioritize compliance assistance with the regulations and TNI for a one-year Implementation Period .
 - c. Continue seeking community input from Stakeholders such as State Regulatory Agencies, various California laboratory analyst and trade associations, TNI, and the Environmental Laboratory Technical Advisory Committee to identify areas in which the State Board can assist laboratories.
 - d. Use third-party assessments as allowed in statute to conduct laboratory assessments. After providing an opportunity for input from Stakeholders, bring back to the State Water Board for approval before the regulations go into effect the terms and conditions third party assessment firms must meet to provide services to laboratories in California, and the process and procedures that laboratories must follow for use of third-party assessors;

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- e. Focus enforcement efforts, during the Transition and Implementation Periods, on compliance assistance and progressive enforcement. Progressive enforcement contemplates an escalating series of actions beginning with notification of violations and compliance assistance, followed by increasingly severe consequences, culminating in formal enforcement. During these periods of Transition and Implementation, formal enforcement actions such as suspension or revocation of accreditation or a monetary citation should be reserved for the most egregious violations, such as those violations resulting from intentional or grossly negligent misconduct, or violations that impact public health and the environment.
 - f. Ensure regulated entities can locate and access accredited laboratories by providing real-time access to accreditation data through an improved electronic database system and mapping tool.
 - g. After the 3-year Transition Period, assess laboratory progress in meeting the regulatory requirements and present this evaluation at a State Water Board Meeting.
6. Directs the Executive Director to sign Form 400 and submit the adopted regulations to OAL for filing with the Secretary of State; and
7. Authorizes the Executive Director or her delegee to make, prior to OAL filing the regulations with the Secretary of State, any non-substantive corrections to the language of the regulations or supporting documentation deemed necessary for clarity or consistency.

CERTIFICATION

The undersigned Clerk to the Board does hereby certify that the foregoing is a full, true, and correct copy of a resolution duly and regularly adopted at a meeting of the State Water Resources Control Board held on May 5, 2020.

Jeanine Townsend
Clerk to the Board